

Application No. 10/589862
Response to the Office Action dated June 23, 2009

REMARKS

Favorable reconsideration of this application is requested in view of the following remarks.

The Specification has been amended to include the limitations in original claims 2, 4, 6, 8, and 10 as the Examiner suggested.

Claim 9 has been amended to depend from claim 1 and clarify that the pigment is an additional component of the composition. Accordingly, claim 10 has been amended to depend from claim 9. Process claim 11 has been amended to include limitations to coincide with product claim 1 and further supported by the specification at page 3, lines 1-4 under "Detailed Description of the Invention" and the paragraph beginning on page 4, line 7. Claim 18 has been amended to recite the range of the methacrylate copolymer content as supported by the paragraph of the specification beginning at page 4, line 7 and example 4 in the table on page 7. Claims 2-18 have been amended editorially.

Claims 1 and 12 filed on April 15, 2009 have been objected to because the specification does not include the limitations of these claims. Applicants note that the methacrylate copolymer content of 40-70 % in original claim 3 is an apparent error and that the content of original claim 2 is 40-75 % by weight of the composition. Applicants further respectfully note that the amendment to claim 1 was filed on March 18, 2009, and claim 12 was added on September 11, 2008. The specification has been amended to add the methacrylate copolymer contents of about 20-90 % by weight (wt%) and 40-75 wt% as supported by original claim 2 as discussed above. Thus, claims 1 and 12, which include the methacrylate copolymer contents of about 20-90 wt% and 40-75 wt%, respectively, are supported by the original disclosure. Accordingly, a new matter has not been introduced to these claims, and this objection should be withdrawn.

Claim 18 has been rejected under 35 U.S.C. 112, first paragraph, as not complying with the written description requirement. Claim 18 has been amended to

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include the range of methacrylate copolymer content of 40-69 % by weight as supported by the specification as discussed above. Accordingly, this rejection is moot and should be withdrawn.

Claims 9 and 10 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Applicants contend that the rejection to claim 10 is improper because the "pigments" are recited in claim 16 from which claim 10 depended.

Claim 9 has been amended to depend from claim 1 and clarify that the claim further includes a pigment selected from the listed materials. Claim 10 has been amended to depend from claim 9 and add a requirement of pigment content to claim 9. Accordingly, these claims are well defined and clear, and this rejection should be withdrawn.

Claims 1-8, 11-15, and 18 have been rejected under 35 U.S.C. 102(e) as being anticipated by Deshpande et al. (U.S. Patent Application Publication No. 2004/0028737). Applicants respectfully traverse this rejection.

Deshpande discloses a bilayer enteric coating, of which an inner layer is neutral or near neutral such as pH 7-7.5 and an outer layer is acidic such as pH 2-6 (see abstract). The reference further discloses examples that include a methacrylate copolymer, polyethylene glycol, titanium dioxide, and talc (see examples 1-4 and 8). To adjust the pH of the inner layer of these examples, Deshpande uses 2M ammonia solution, i.e., an alkalinizing agent, which is excluded from claim 1. Thus, the enteric film coating dry power composition of claim 1 is distinguished from the inner layer of Deshpande.

In addition, Deshpande fails to disclose the outer layer that includes a methacrylate copolymer of Type C, a plasticizer, a film coating detackifier, and an opacifier and no alkalinizing agent as claim 1 recites. Further, the reference discloses that the outer layer coating is carried out using an aqueous dispersion of the enteric material (see para. [0037]) and that examples 1-4 and 8, which include methacrylate copolymer, polyethylene glycol, titanium dioxide, and talc in the inner layer, contain 3 %

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w/v castor oil in the outer layer, and thus Deshpande also fails to disclose the outer layer that is a dry power composition as claim 1 recites (see examples 1-4 and 8).

Accordingly, claim 1 and claims 2-8, 12-15, and 18, which depend from claim 1, are distinguished from Deshpande.

Claim 11, which is a process claim corresponding to product claim 1, is distinguished from Deshpande for at least the same reasons as discussed for claim 1 above.

Accordingly, this rejection should be withdrawn.

Claims 9, 10, 16, and 17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. (U.S. Patent Application Publication No. 2004/0028737) in view of Kokubo et al. (U.S. Patent No. 4,948,622). Applicants respectfully traverse this rejection.

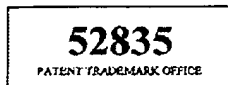
Claims 9, 10, and 16, which ultimately depend from claim 1, and claim 17, which depend from claim 11, are distinguished from Deshpande for at least the same reasons as discussed for claims 1 and 11 above.

Kokubo discloses a coating of pharmaceutical formulations, such as granules, beads, and tablets, with a hot aqueous dispersion of a cellulose ether and then wax with heat (see abstract). Thus, Kokubo fails to disclose the enteric film coating dry power composition that includes a methacrylate copolymer, a plasticizer, a detackifier, an opacifier, and no alkalizing agent as claims 1 and 11 recite, and Kokubo does not remedy the deficiencies of Deshpande.

Accordingly, Claims 9, 10, 16, and 17 are distinguished from Deshpande in view of Kokubo and this rejection should be withdrawn.

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In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.



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DPM/my/jls

Respectfully submitted,

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